K002707

PVS
PRECISION VASCULAR SYSTEMS Inc.
360 Wakara Way
Salt Lake City, UT 84108

NOV - 8 2000

510(k) Summary

1. **Device Name:**

Trade Name: PVS 1400 Guide Wire with hydrophilic coating

Common Name: Guide Wire

Classification Name: Catheter, Guide Wire

2. **Establishment Name and Registration Number:**

Name: Precision Vascular Systems, Inc.

Number: 1724618

3. **Classification:**

WIRE, GUIDE, CATHETER 74DQX II 870.1330

870.1330 Catheter guide wire. (a) *Identification.* A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. (b) *Classification.* Class II (performance standards).

Device Classification:	Class II
Classification Panel:	Cardiovascular
Product Code:	74DQX

3. **Special Controls:**

Not applicable to this device.

4. **Labeling**

Important: Draft labeling is provided in Appendix I.

Warnings and Cautions	Please see Appendix I
Contraindications	Please see Appendix I
Precautions	Please see Appendix I

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Preparations for use	Please see Appendix I
Directions for use	Please see Appendix I
Packaging & Product Information	Please see Appendix I
Product Information Disclosure	Please see Appendix I

5. Class III Certification:

Class III certification is not applicable to this device.

6. Photographs:

Please see Appendix II for graphics of the device

7. Drawings:

Please see Appendix II for drawings of the device.

8. Equivalent/Predicate Devices:

PVS 1400 Guide Wire (K 990823)

9. Device Description:

The PVS 1400 Guide Wire with hydrophilic coating is a 0.014" outside diameter, single use guide wire, which is used in percutaneous procedures to introduce and position catheters and other interventional devices within the coronary and peripheral vasculature. A torque device is included as a component. The tip section is Nitinol. The device is sold as sterile and non-pyrogenic. Refer also to the description in Appendix V.

Materials: The core wire is stainless steel. A Platinum wire is used for improved radiopacity. The guide wire is coated to provide lubricity. The tip material of the guide wire is Nitinol. Refer also to the material description in Appendix II for a comprehensive listing of materials.

Instrumentation: There is no instrumentation applicable to this device.

10. Modified Device Data:

This section is not applicable to this device.

11. Applicant's Name and Address:

Precision Vascular Systems, Inc.
360 Wakara Way
Salt Lake City, Utah 84108
801-585-3430 Telephone
801-585-7906 Fax

12. Company & Submission Contact:

John R. Ragazzo
Precision Vascular Systems, Inc.
360 Wakara Way
Salt Lake City, Utah 84108
801-585-7069 Telephone
801-585-7906 Fax

13. Manufacturing Facility:

The device will be manufactured at the company facility at 360 Wakara Way, Salt Lake City, Utah 84108.

14. Comparison Table:

Please refer to Appendix IV, Rationale for Substantial Equivalence

15. Voluntary Standards:

United states Food and Drug Administration-mandated performance standards for this device do not exist. This device and its methods of manufacture comply with applicable harmonized standards and Quality System Regulation (21 CFR Part 820) and ISO 9001/EN 46001 Medical Device Directive 93/42/EEC requirements.

16. Performance Data:

The PVS 1400 Guide Wire performance was compared to predicate devices for tensile strength, torque strength, torqueability, tip flexibility, coating adherence/integrity, and catheter

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compatibility. Please refer to Appendix III for results of testing on the PVS 1400 Guide Wire with hydrophilic coating.

Tensile Strength- The PVS 1400 Guide Wire with hydrophilic coating showed slightly higher average tensile results than the predicate device. The results were within the expected variability of test results. All results were above specification requirements.

Torque Strength- The PVS 1400 Guide Wire with hydrophilic coating had slightly higher average torsion strength than the predicate device. The results are within the expected variability of this data. The minimum torsion strength was slightly lower but above specification requirements.

Torqueability & Turns to failure- Torqueability is not a directly measurable characteristic. It is a relationship between the distal end rotation from an arbitrary proximal end input rotation. The average delta value for the PVS 1400 Guide Wire with hydrophilic coating was 185°. The average delta value for the predicate device was 160°. With consideration to the test method, a 25° difference is insignificant. The turns-to-failure results show the PVS 1400 with hydrophilic coating and the predicate are within one turn on the average results. The PVS 1400 Guide Wire with hydrophilic coating had lower results on the minimum and maximum turns-to-failure than the predicate device. These results are consistent with expected variability of these measurements and variability of the process.

Tip Flexibility- The PVS 1400 Guide Wire with hydrophilic coating had slightly higher test results than the predicate device in small distances from the tip. These results are comparable and acceptable.

Coating Adherence/Integrity- PVS has adopted the use of USP 23, Second Supplement, Particle Test Count & Light Obscuration Particle Count test to assess particles to pass-fail criteria. The PVS 1400 Guide Wire with hydrophilic coating passes this USP test criteria using the Light Obscuration Particle Test Method. PVS routinely performs monitoring tests. Tests performed on the predicate device also passed the USP 23 Light Obscuration Particle Count test criteria.

Catheter Compatibility- This test is an outcome of applying the test method in PVS Coating Monitoring procedure 10-04-00 in Appendix III. The PVS 1400 Guide Wire with hydrophilic coating is compatible with the catheters tested as was the predicate device based on the functionally acceptable results obtained by multiple insertions of the guide wires into the catheters. Particle count test results further demonstrate acceptable performance for the PVS 1400 Guide Wire with hydrophilic coating and the predicate device. See Appendix III for test results.

Coating Flake/Adhesion – The PVS 1400 Guide Wire with hydrophilic coating demonstrated no coating flaking or peeling results when viewed at 40X magnification. Results showing that no

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patches were removed indicate that the device is substantially equivalent or better than guidewires with hydrophilic coating. See results in Appendix III.

Biocompatability data- The PVS 1400 Guide Wire with hydrophilic coating was biocompatibility tested per FDA guidance for an external device in contact with circulating blood for less than 24 hours. Tests performed include Cytoxicity, Systemic Toxicity, Irritation, Sensitization, and Hemocompatibility (comprising Hemolysis and Thrombogenicity). The biocompatability test results were acceptable and establish that the PVS 1400 Guide Wire with hydrophilic coating is biocompatible. See Appendix III for data.

Limulus Amebocyte Lysate- LAL testing was performed and the detected endotoxin is less than the maximum allowable endotoxin level of ≤ 20 EU/device. See Appendix III for details.

17. Storage, Packaging, and Sterilization Information:

Storage and Handling: Store in a cool, dark, dry place.

Packaging: Inspect all packaging upon receipt for evidence of damage. Do not use open or damaged packages. The expiration date for sterilization must be checked on the package label prior to use. Only those products, which are to be used prior to shelf-life expiration date, may be considered sterile. Every precaution should be taken to ensure sterility when opening the device's packaging. Damaged packaging may render the product unsafe for use.

Sterilization: The guide wires are supplied pre-sterilized by gamma radiation. The selected radiation dose is 25 kGy or greater. The Sterility Assurance Level (SAL) is 10^{-6} or greater. The device is not intended to be cleaned or resterilized by the user. The product will be sterilized per the requirements of ISO 11137.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2000

Mr. John R. Ragazzo
Precision Vascular System, Inc.
360 Wakara Way
Salt Lake City, UT 84108

Re: K002707
Trade Name: PVS 1400 Guidewire with Hydrophilic Coating
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: August 26, 2000
Received: August 30, 2000

Dear Mr. Ragazzo:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Miriam C. Provost for

James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Precision Vascular Systems, Inc.

PVS 1400 Guidewire with Hydrophilic Coating

Indications for Use

510(k) Number (if known): K002707

Device Name: **PVS 1400 Guidewire with Hydrophilic Coating**

Indications for Use:

1. These guidewires are intended for use in percutaneous procedures to introduce and position catheters and other interventional devices within ~~the coronary~~ and peripheral vasculature.
2.
3.
4.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002707

Prescription Use ✓ OR Over-the-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)